

POINT OF CARE
TESTING

Accutrend® GC



CE 0088



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Germany
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User's Manual



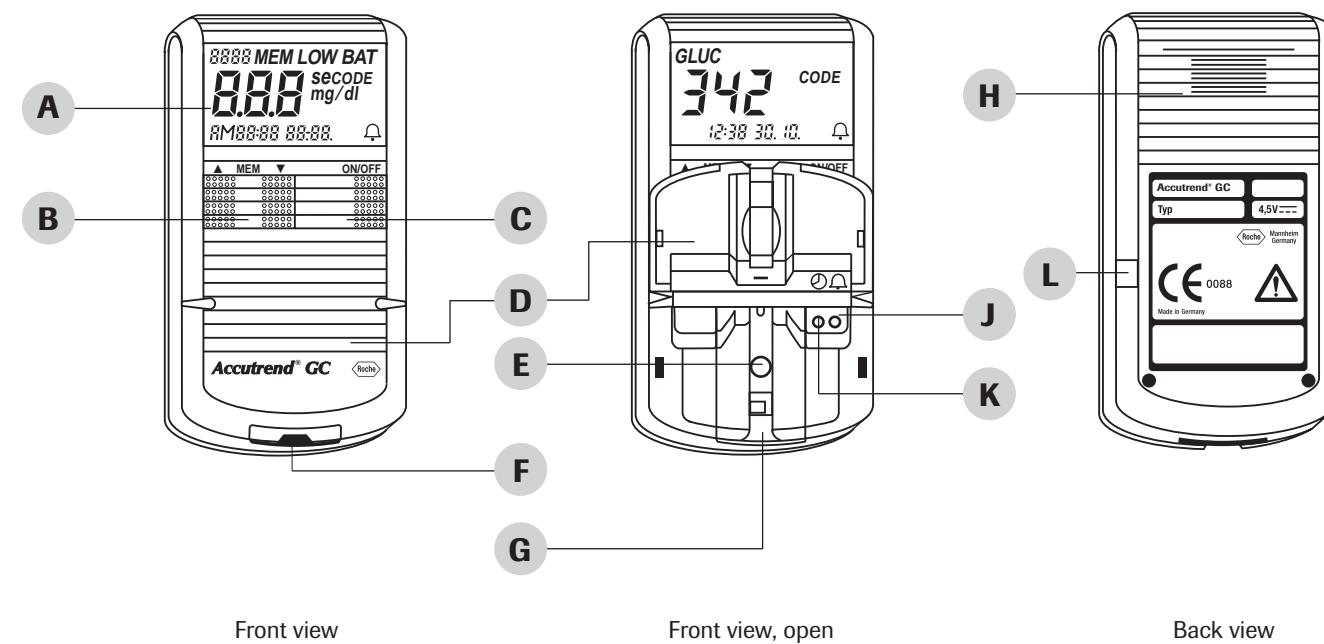
Last updated: October 2000

The abbreviations used by the Accutrend® GC are shown below with their respective meanings:

| | |
|---------------|--------------------------------------------|
| CODE | code number of the test strip batch in use |
| GLUC | glucose = blood sugar |
| CHOL | cholesterol |
| MEM | memory |
| SET | setting |
| AM | morning |
| PM | afternoon |
| LO | low, value below measurement range |
| HI | high, value above measurement range |
| E, EEE | error |
| CL | clear/delete |
| ALL | all |
| ON | on |
| OFF | off, outside range |

Instrument components and display elements

All components and display elements are explained fully in the manual. It is best to have your instrument next to you while reading the manual and to try out each step as it is described.



Description

A Display

All display elements are shown.

B Rocker button

The button ▲ MEM ▼ has several functions.

C ON/OFF button

The right button switches the instrument on and off.

D Flap

Protects the optics.

E Measurement window

The measurement is carried out here.

F Slot for test strip

The test strip is inserted in the slot at the bottom of the meter.

G Test strip guide

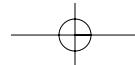
Holds the test strip in the correct position.

H Battery compartment lid

J Beeper button

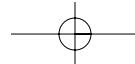
K SET button for time and date

L Connector for data transmission



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Please read this manual carefully and completely before performing the first measurement.

The packaging material, the identification plate on the instrument and the manual may contain the following symbols or abbreviations:



For in vitro diagnostic use



This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic devices



Order/catalogue number



Please consult instructions for use



Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument



Manufactured by

1. Introduction

Accutrend® GC is a modern, reliable, and easy-to-use instrument for the determination of two important blood parameters: glucose and cholesterol. Using the proven test-strip principle, Accutrend® GC allows rapid monitoring of these blood values. Accutrend® GC is also suitable for self-testing. With Accutrend® Glucose you can determine your blood sugar in only 12 seconds and with Accutrend® Cholesterol you can determine your cholesterol level in 180 seconds.

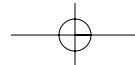
The instructions below take you step by step through the meter's operation, cleaning and care. Please take time to read the instructions and practise using the instrument. Fold out the page with the description of the instrument components. These components, indicated by letters of the alphabet, are referred to frequently in the text. The fold-out page is a helpful orientation.



Warning! You will find this sign when there is a potential danger to health, e.g. the danger that you might calculate the insulin dose incorrectly.



Caution! You will find this sign when there is a danger that you might damage the device, e.g. through improper cleaning.



2. Using Accutrend® GC for the first time

2.

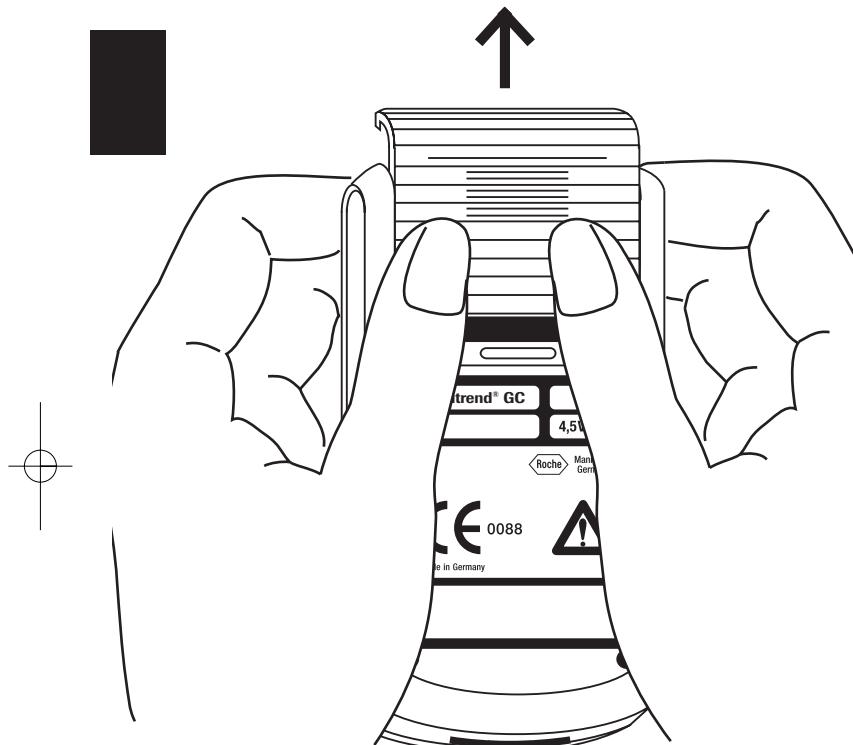
Accutrend® GC is supplied with a storage pouch, 3 batteries and these operating instructions. If any of these items are missing or damaged please contact your supplier.

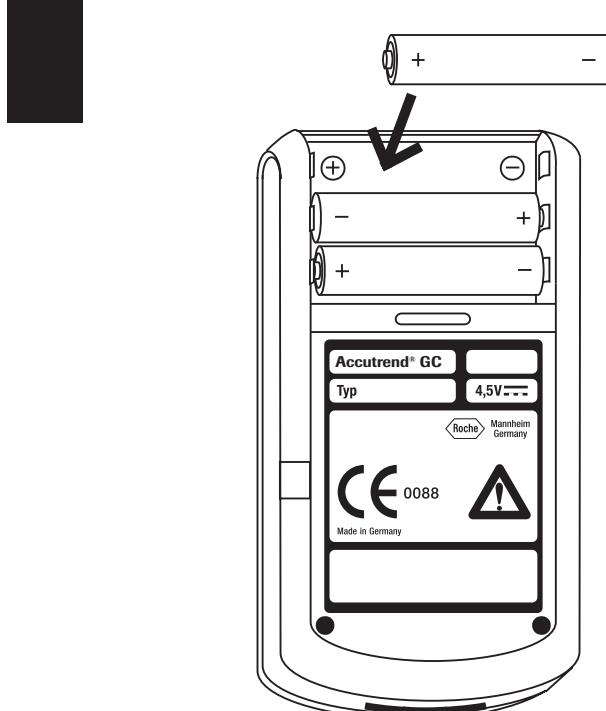
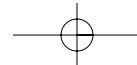
2.1 Inserting/changing the batteries

Accutrend® GC is supplied with three AAA alkaline manganese batteries. The batteries must be inserted before using the meter.

Procedure for inserting/changing the batteries:

- Always switch off the Accutrend® GC before inserting or changing the batteries. Then turn the meter over and hold it with both hands.
- Slide the battery compartment lid **H** gently in the direction of the arrow using both thumbs and remove.





- ▶ Take out old batteries if necessary.
- ▶ Insert the new batteries, making sure that the terminals are the right way round (shown by the \oplus symbols in the battery compartment and on the battery).
- ▶ Replace the battery compartment lid **H** and slide it closed until it locks into place.
- ▶ Press the ON/OFF button **C** to check that the batteries have been inserted correctly. A function test lasting 2 seconds appears on the display (see Section 2.2).

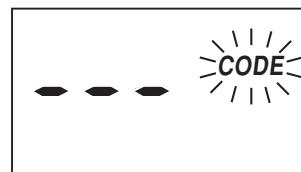
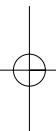
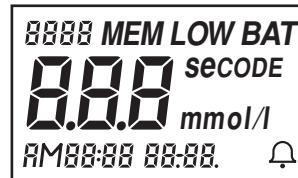
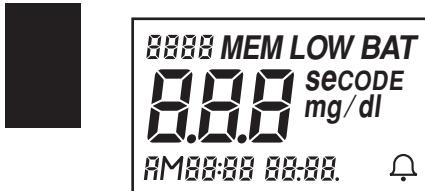
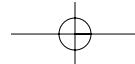
2.

Accutrend® GC switches off automatically after one minute if none of the buttons have been pressed during this time.

2.2 Switching on the meter for the first time

After you have inserted the batteries, you can switch on the meter using the ON/OFF switch **C**. Immediately after switching on, the meter always performs an automatic function test lasting about 2 seconds, checking all instrument functions and display elements. No entries can be made during this test. The automatic function test is performed every time the instrument is switched on using the ON/OFF switch **C** with the flap closed.

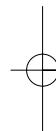
When the Accutrend® GC is switched on for the first time, you should check each display element during the function test. To do this follow the instructions given below.



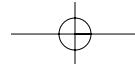
Procedure for checking the display elements during the function test

- ▶ Before switching on the meter, open the flap **D** by gently pressing at the bottom edge. The respective display elements will now remain displayed for a longer time.
- ▶ Check whether the units displayed are the ones required. Depending on the version of the instrument the display will show either **mg/dl** (milligrams per decilitre) or **mmol/l** (millimoles per litre) If you are not sure whether you require **mg/dl** or **mmol/l** please ask your doctor.
If the unit you are familiar with does not appear in the display, please ask your dealer to exchange the instrument.
- ▶ Make sure that all three digits of the display appear as **888**. If any of the lines making up these digits are missing, the values displayed later might be incorrect.
- ⚠ If at any time during the function test the display does not correspond to either of the diagrams on the left, please notify the Roche Diagnostics service (see pages 97 and 105).
- ▶ Close flap **D** again, exerting slight pressure.

2.



When the function test is complete the word **CODE** flashes and **---** is displayed.



2.

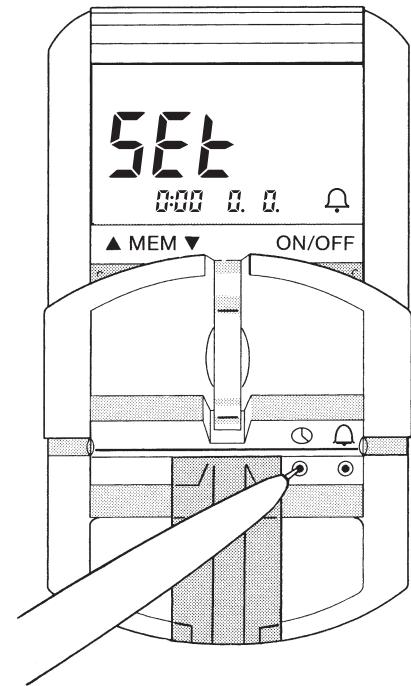
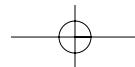
2.3 Setting the time and date

The time and date of the Accutrend® GC can be set and changed. The time must also be changed from summer to winter time and vice versa, and 29 February must be entered in a leap year. The buttons are recessed to protect them from being pressed inadvertently. To operate these two buttons you can use – for example – a ballpoint pen.

For your data to be stored with the important information “date and time”, these must first be set correctly.

The time can be displayed in either the 12-hour or 24-hour format. If the 12-hour format is chosen, the time is displayed as numbers from 1 to 12 with the addition of AM (before 12 noon) or PM (after 12 noon), e.g. **PM 3:43**. If the 24-hour format is chosen, the time is displayed in numbers from 1 to 24, e.g. **15:43**.

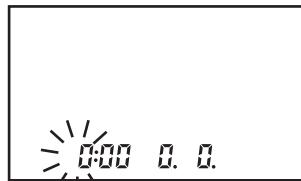
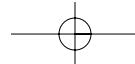
The default setting for Accutrend® GC is the 24-hour format. The following instructions describe how to change it to the 12-hour format.



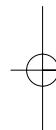
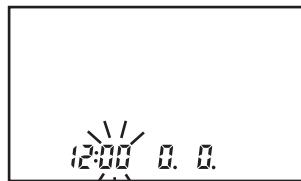
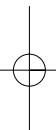
Procedure for setting time and date

- Switch the Accutrend® GC on using the ON/OFF button **C** and wait until the function test is complete.
- Open flap **D**. **SET** appears on the display **A**.
- Briefly press the SET button **K** below the clock symbol **⌚**, using a ballpoint pen, for example. Time and date begin to flash in the display.
- To change the display from the 24-hour to the 12-hour clock format gently lift up the flap **D** and press the rocker button **▲ MEM ▼ B**. **AM** or **PM** appears on the display.

2.



2.

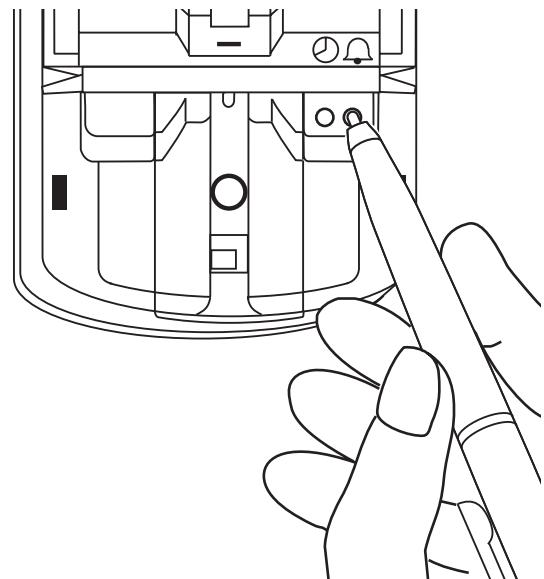
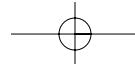


- ▶ Press the **SET** button briefly. The hours flash on the display.
Keep pressing **▲ MEM ▼ B** until the desired hour is displayed.
- ▶ Press the **SET** button briefly. The minutes flash on the display.
Keep pressing **▲ MEM ▼** to set the minutes in the same way as the hour.
- ▶ Press the **SET** button briefly. The day flashes on the display.
Keep pressing **▲ MEM ▼** to set the day in the same way as the hour.
- ▶ Press the **SET** button briefly. The month flashes on the display.
Keep pressing **▲ MEM ▼** to set the month in the same way as the hour.
- ▶ Store the changes by closing flap **D** or by pressing the **ON/OFF** button **C**. Your settings will be stored automatically.

Leap year

In a leap year the date will not change automatically from 28.02 to 29.02 but to 01.03. In order to change the date, proceed as described above.

The date will then change automatically from 29.02 to 01.03.



2.4 Switching the beeper on and off

The beeper signals provide useful support.

For example, Accutrend® GC uses one beep to confirm successful coding and a series of beeps to indicate the approaching end of a measurement.

If the beeper is switched on, the bell symbol appears to the right of the date. We recommend leaving the beeper switched on. However, if you find the sound annoying you can switch off the beeper as follows.

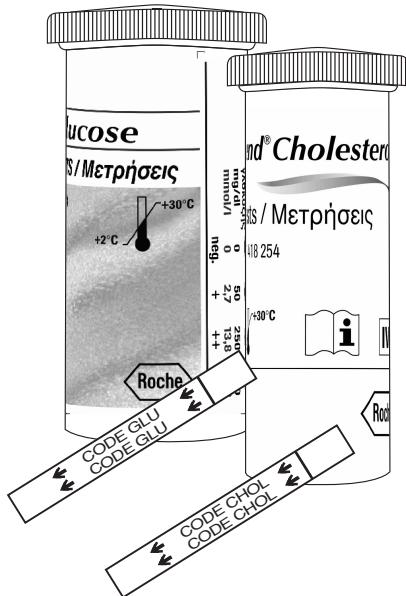
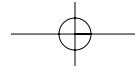
2.

Procedure for switching the beeper on and off

- Switch on the meter with the ON/OFF button **C** and wait until the function test is complete.
- Open flap **D**. **SET** appears on the display **A**.
- Press the beeper button **J** briefly using a ballpoint pen. The bell symbol disappears.
- Close the flap.

Switch off the meter. The setting will be stored automatically.

You can switch the beeper back on again at any time by following the procedure described above.



3. Performing a measurement with Accutrend® GC

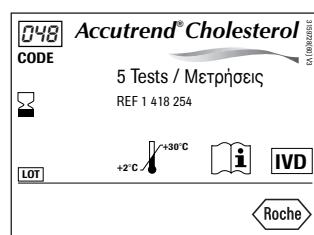
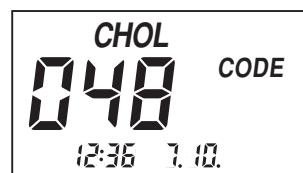
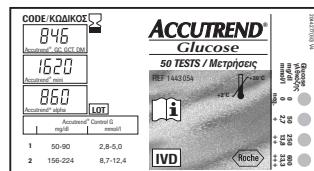
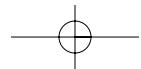
3.1 Coding of the meter

The properties of the test strips can vary slightly from pack to pack. Accutrend® GC must therefore be adjusted to accommodate these differences. This adjustment is referred to as coding.

It is performed with the help of code strips which enter the specific characteristics of the respective Accutrend® Glucose and Accutrend® Cholesterol strips used. Accutrend® GC must be coded:

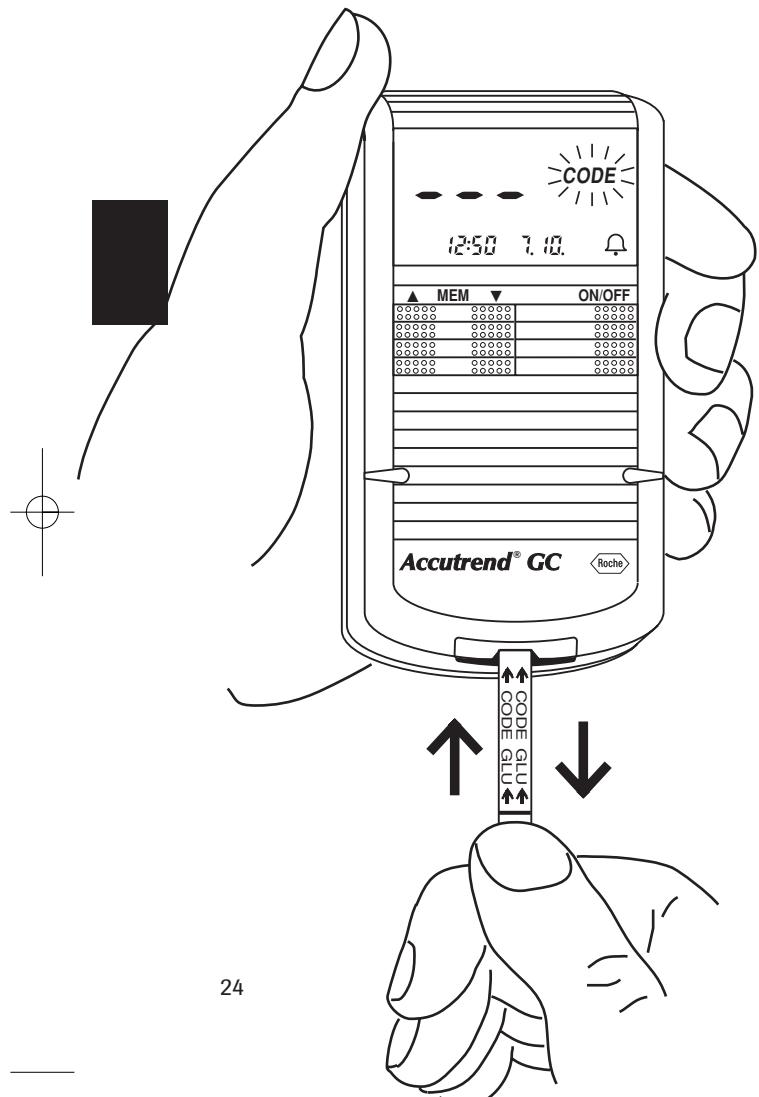
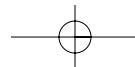
- After switching on for the first time, when no code number is stored in the meter.
- Whenever a new pack of test strips is used. The instrument is coded only for the pack from which you take the test strips for the measurement of blood glucose or cholesterol. Individually wrapped code strips are included in each pack of strips.

3.



During each measurement the coded meter performs the essential checks automatically. Since each code strip and test strip is characterized by a bar code on the back, the meter recognizes whether a blood glucose (**GLUC**) or cholesterol (**CHOL**) strip is being used. It then checks automatically whether the code number on the inserted test strip is the same as the code number it has stored. If the wrong test strip is inadvertently used, the error message **E- /** appears.

3.

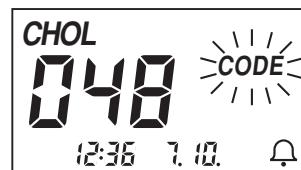
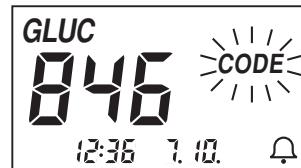
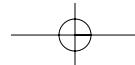


Procedure for coding Accutrend® GC

- ▶ Switch on the meter. When the function test is complete the word **CODE** flashes. If the instrument has not been coded before, the display shows ---. If it has been coded previously, the "old" three-digit code is displayed.
- ▶ Take the code strip out of the wrapping and hold it between the thumb and forefinger with the arrows pointing away from you. Be careful not to touch the black horizontal line.
- ▶ With the flap **D** closed, insert the code strip into the slot **F** in one smooth, brisk movement as far as it will go, then withdraw the strip immediately. If the beeper is switched on, successful coding is acknowledged by a beep. The display shows a three-digit code number. The code has been read in and stored.

3.

If the error message **E-2** or **E-3** appears, coding was unsuccessful (see Section 6.1). In this case, repeat the coding as follows: open flap, close flap, insert code strip and then withdraw again immediately.

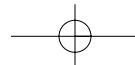
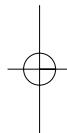
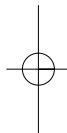


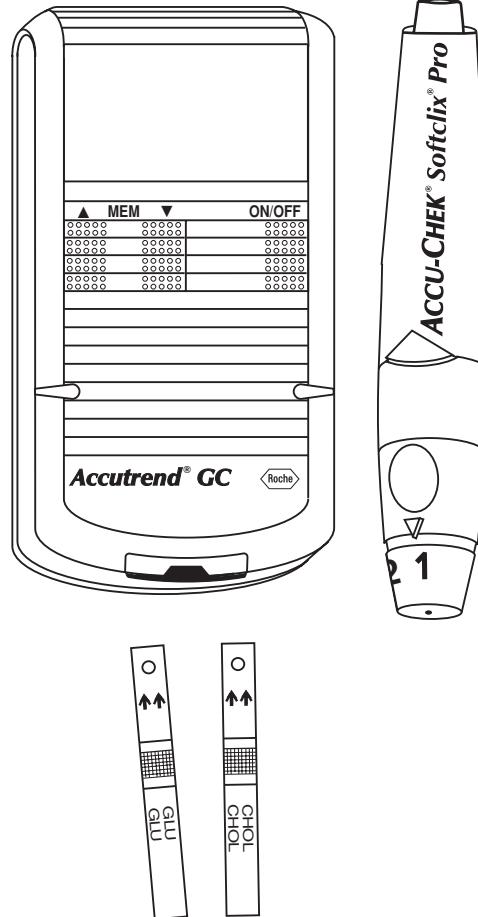
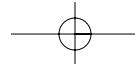
After coding a measurement can be carried out with any test strip whose code number is stored in the meter. When the test strip is inserted the display automatically switches to the correct symbol for the strip.

After coding do not throw away the test strip in case recoding is necessary later on.

3.

Store the code strip in its wrapping and not in the test strip container because the print on the code strip may impair test strip quality and lead to erroneous results.





3.2 Measuring glucose and cholesterol

3.2.1 Practising measurement

If you have little or no experience of self-monitoring and want to get used to using the meter and the test strips you can practise measuring without a blood sample. The procedure is identical to that for checking the performance of the meter; go to Chapter 5.1 "Checking the Measurement System" and follow the instructions given there.

3.

3.2.2 Performing a measurement

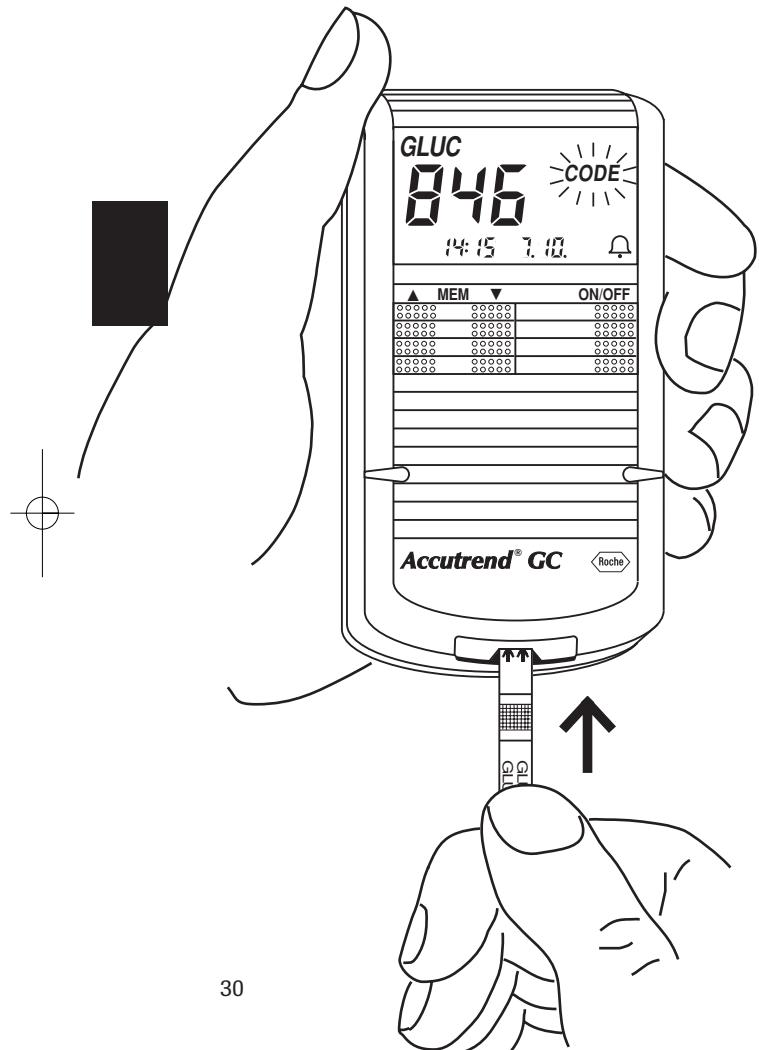
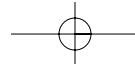
To perform a measurement you require:

- The Accutrend® GC meter which you have already coded; you have also set the time, date and beeper.
- Accutrend® test strips (Accutrend® Glucose for blood glucose measurement; Accutrend® Cholesterol for determination of cholesterol).
- A lancing device (e.g. Accu-Chek® Softclix® Pro with Accu-Chek® Softclix® Pro Lancet).
- Possibly alcohol wipes and cellulose pads.

Procedure

⚠ Carefully read the pack inserts that come with the test strips and the lancing device.

⚠ **Warning!** If measurements are performed on several persons there is a potential risk of infection (e.g. hepatitis, AIDS). Before using the meter for another person it

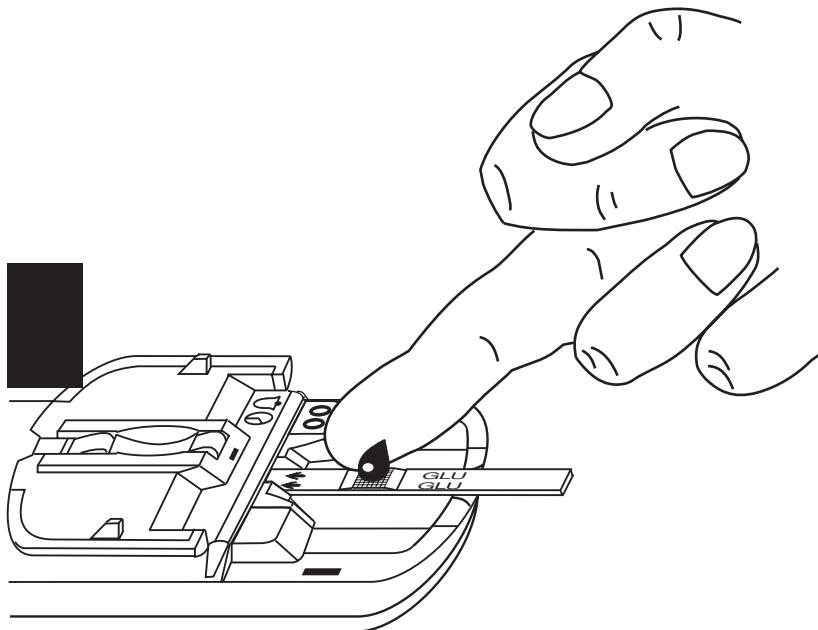
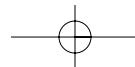


must be cleaned and disinfected each time (see Section 5). Please read the detailed description in Section 3.3 if you are performing measurements on several persons.

Users in the office and laboratory sector should note that samples containing human material must be handled as potentially infectious material. Please observe the appropriate regulations and guidelines.

3.

- ▶ Wash and dry your hands thoroughly.
- ▶ Prepare the lancing device.
- ▶ Switch on the Accutrend® GC. When the function test is complete **GLUC** or **CHOL** appears – or **GLUC** and **CHOL** alternately if the meter has been coded for both. The corresponding code number, the time and the date appear below. The word **CODE** flashes and the Accutrend® GC is now ready for the measurement of the coded parameters.
- ▶ Take a test strip out of the test strip container. Close the container immediately otherwise the desiccant in the stopper will be exhausted and the test strips will become unusable.
- ▶ With flap **D** closed, insert the strip into the slot **F** in the direction of the arrow with the square yellow test area facing upwards until the strip locks into place and the inscription **GLU** or **CHOL** on the test strip is no longer visible.

**Incorrect**

Test area on top of the strip incompletely covered with blood.

**Correct**

Test area on top of the strip completely covered with blood.

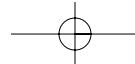


Successful reading of the test strip code is indicated by two beeps (one short, one long), if the beeper is switched on, and by display of the test strip type: either **GLUC** or **CHOL**. Then **CODE** stops flashing.

3.

If the strip code has not been read in correctly, error messages appear (e.g. **E-1**, **E-2**, or **OFF**). In this case, consult Section 6.1 "Error messages" and follow the instructions given there. If the inserted strip is not shown correctly on the display (e.g. if **GLUC** is not displayed although you have inserted an Accutrend® Glucose test strip), switch off the meter and start again.

- ▶ Open the flap.
The measurement time in seconds flashes on the display: **12 sec** for **GLUC**, **180 sec** for **CHOL**.
- ▶ Rub and knead the side of a fingertip to facilitate the withdrawal and application of blood.
- ▶ Lance the massaged site with the lancing device.
- ▶ With the test strip still in the meter, allow a hanging drop of blood to form without applying too much pressure. For determination of cholesterol wipe off the first drop of blood with a cellulose pad and use the second drop of blood for the test. Carefully apply the drop of blood to the yellow test area (pad) on the strip without touching the test pad directly with the finger.



3.



The test pad must be completely covered with blood, otherwise the results obtained may be incorrect (i.e. too low). If too little blood is applied, do not try to spread it or apply a second drop as this may also produce incorrect results. Repeat the measurement with a fresh test strip.



Close the flap immediately after applying the drop of blood. The display now counts down in seconds to **0**. During the last four seconds a series of beeps is heard (one beep per second), followed by a longer beep at the end of the measurement. The measured value (in **mg/dl** or **mmol/l**) appears on the display **A**. The result is stored.

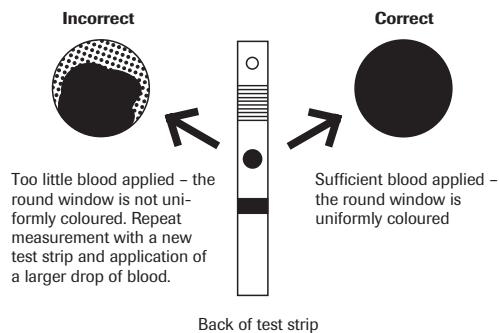
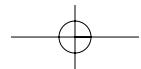
Accutrend® GC measures values only within certain ranges:

glucose 20–600 mg/dl (1.1–33.3 mmol/l)

cholesterol 150–300 mg/dl (3.88–7.76 mmol/l).

If the value obtained is above these ranges the meter displays **H** (= high), if the value obtained is below these ranges the meter displays **L** (= low).

The meter also displays **L** when too little blood is applied, i.e. if the yellow test pad is not completely covered with blood. If this message appears, you should therefore turn the test strip over and check whether the round window on the back is uniformly coloured. If it is only partly coloured, the measurement must be repeated with a new test strip.



The round test window must be completely covered with blood, otherwise the results obtained may be incorrect. This can lead to inappropriate treatment recommendations and thus endanger your health.

If other messages appear on the display, consult Section 6.1 "Error messages" and follow the instructions given there.



Open the flap and take out the test strip.

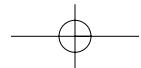
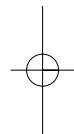
Always open the flap before removing the test strip so as to avoid soiling the instrument. The meter switches off automatically after about 1 minute if no button has been pressed or the flap has not been opened during this time. If there is a test strip in the meter Accutrend® GC switches off after 2 minutes. The result is nevertheless stored.

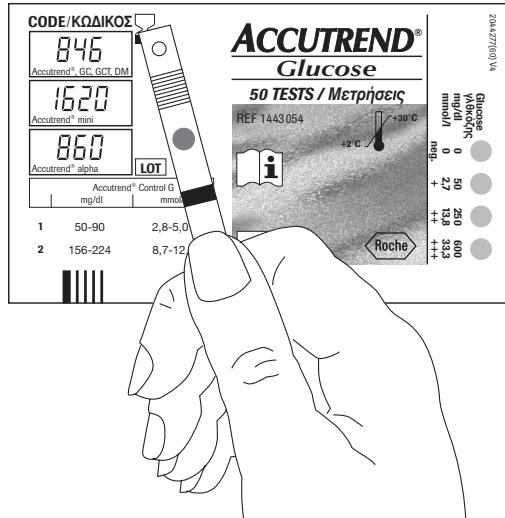
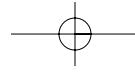


For blood glucose measurements only: perform a colour comparison to check plausibility.

- Turn over the test strip
- Compare the colour in the round window with the colour scale on the label of the test strip container. The colour in the round window must approximately match the colour given for your result and the window must be uniformly coloured.
If the colours do not match, please carry out a performance check (Section 5.1).

3.





The colour comparison only serves as a plausibility check. Treatment decisions should only be based on the result measured by the meter.



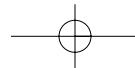
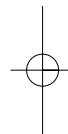
The blood glucose determination is part of the treatment plan agreed on together with your doctor. You should therefore follow the doctor's treatment recommendations. If you receive unexpected or implausible results or if the value shown does not reflect your subjective physical condition you should check the performance of the meter (see Section 5.1). If this shows that the meter is functioning properly, please consult your doctor for advice.

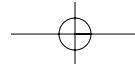


Close the flap and switch off the meter.

The used test strips and other consumables (e.g. cleansing pads, lancets) should be disposed of as household waste. In the medical setting, e.g. laboratory or doctor's surgery, the relevant regulations or guidelines for the disposal of potentially infectious materials must be observed.

3.



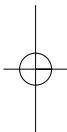
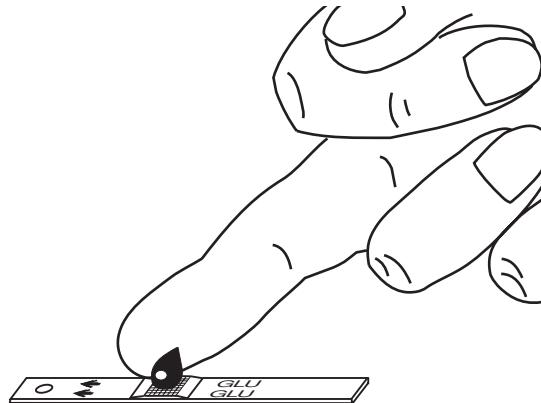
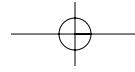


3.

3.3 Measurements on several people

If the Accutrend® GC is to be used in the medical sector for measuring blood glucose and cholesterol in several different persons, special measures must be observed. The blood must be applied to the test strips outside the meter. This is very important as otherwise the flap and test-strip guide may become contaminated with blood residues and there is a risk of infection.

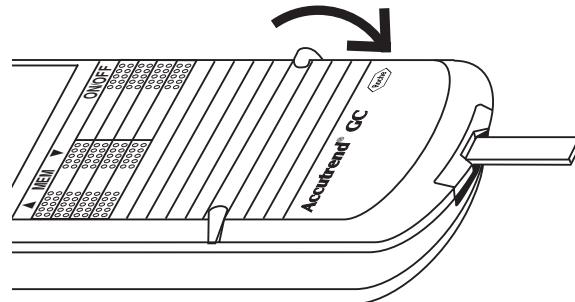
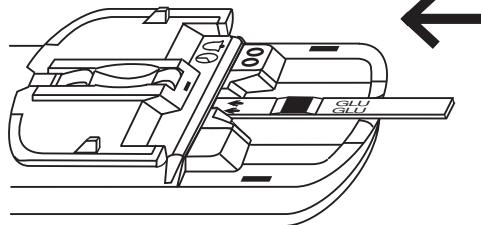
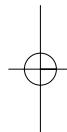
- ⚠ In order to prevent infection (e.g. hepatitis or AIDS) it is essential to observe the following points:
 - ▶ Only apply the blood outside the meter. Follow the instructions in the section "Procedure for measurement on several people" below.
 - ▶ Use a separate lancet and lancing device for each person. We recommend using the Accu-Chek® Softclix® Pro lancing device and Accu-Chek® Softclix® Pro Lancet, which were specially developed for this purpose.
 - ▶ Disinfect the meter with 70% alcohol after each measurement (see Section 5.2).



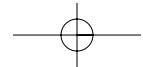
Procedure for measurement on several people

- ▶ Begin as described in Section 3.2.
- ▶ Open the flap.
- ▶ After lancing the finger remove the test strip from the open meter and place on a piece of clean, absorbent material, e.g. paper towel. Then apply the drop of blood as described.
- ▶ **Immediately** re-insert the test strip and close the flap.
- ▶ Continue as described in Section 3.2.

Repeat the described procedure for the next person to be tested, using a new piece of paper towel or similar absorbent material.

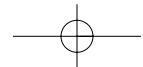
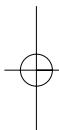
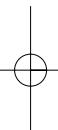


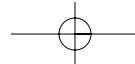
If Accutrend® GC is used for performing measurements on several people and the blood is **always** applied to the strip using an application device (e.g. capillary pipettes) the sample may also be applied with the test strip in the instrument (see Section 3.2). In this case a new application device must be used for each measurement.



Hospital and laboratory users should note that specimens containing human material are to be handled as potentially infectious material. The relevant regulations or guidelines applying to your institute or laboratory should be observed.

The used test strips and consumables (e.g. lancets, swabs) are to be disposed of as potentially infectious waste according to the relevant regulations or guidelines applying to your institute or laboratory.





4. Storing results in memory

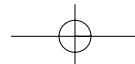
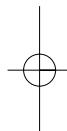
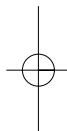
4.1 Automatic storage of results

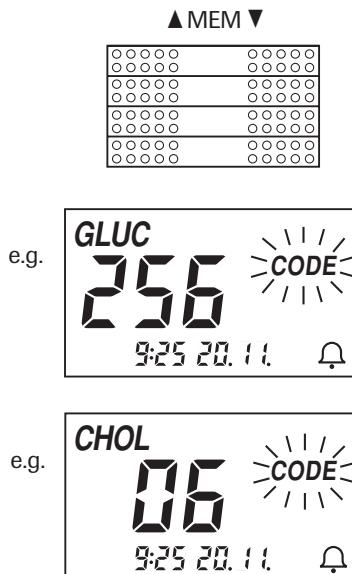
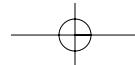
Accutrend® GC automatically stores the blood glucose and cholesterol readings in separate directories. Safety warnings such as *LO*, *HI* or *EEE* are also stored. If the date and time have been set (Section 2.3), these are displayed as additional information with each individual value.

Accutrend® GC stores:
up to 50 blood glucose values in the GLUC directory,
up to 15 cholesterol values in the CHOL directory.
All values stored in the memory **MEM** can be retrieved or deleted.

When you perform a measurement, the Accutrend® GC automatically stores this latest result in the position *01* in the corresponding directory. The previous value is moved automatically to position *02*. Thus, the higher the number of the memory position, the older the value occupying this position. When all available memory positions are occupied, the next measurement automatically leads to deletion of the oldest value from the directory and the latest value is stored in memory position *01*.

4.

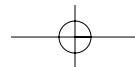




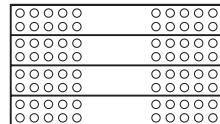
4.2 Retrieving results from memory

- ▶ Switch on the meter and wait until the function test is complete. As soon as **CODE** starts flashing in the display **A**, values can be retrieved from the memory.
- ▶ Select the relevant directory by pressing **MEM ▲** for glucose values or **MEM ▼** for cholesterol values. If no results have been stored, the display will show **00**. If **0 1** is displayed this means that there is at least 1 value in the memory.
- ▶ Release the **MEM** button. The last result stored will appear on the display.

4.



▲ MEM ▼



GLUC MEM

01

10:10 6. 3. ☺

GLUC MEM

95 mg/dl

10:10 6. 3. ☺

GLUC MEM

02

12:09 2. 3. ☺

e.g.

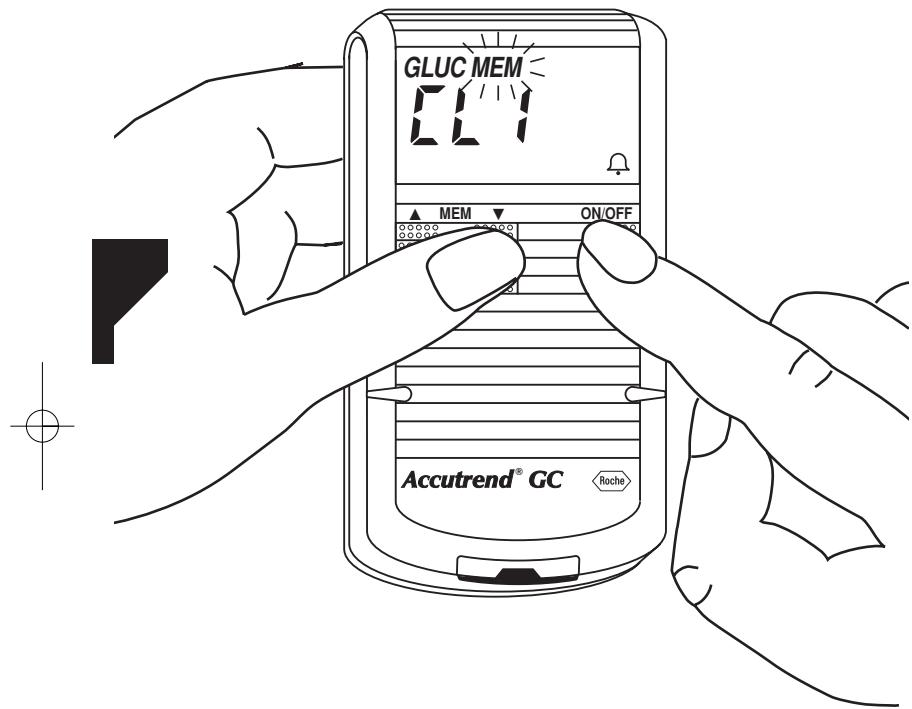
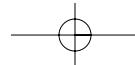
To retrieve values stored earlier proceed as follows:

- ▶ Press the button MEM ▲ and hold it down to run through all memory positions. When all positions have been shown the display returns to **1.**

To count down from any value stored:

- ▶ press the button MEM ▼.
- ▶ To terminate the retrieval procedure press the ON/OFF button **C**.

4.



4.3 Deleting results from memory

The automatically stored values can also be cleared from the memory. You have the following possibilities:

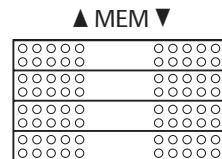
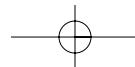
- a) clearing the most recent value stored
- b) clearing all values stored in one directory.

Note that these two steps can only be performed one after the other in the given order.

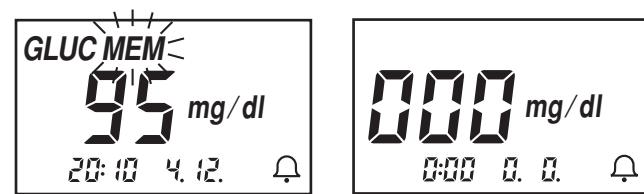
4.

Clearing the most recent value stored

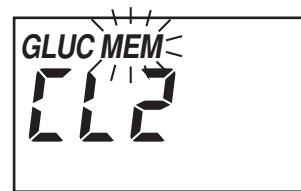
- Switch off the meter. While holding down the MEM **▲** button for the glucose values or the **▼ MEM** button for the cholesterol values, briefly press the ON/OFF button **C**. Release the MEM button. **MEM** flashes in the display **A** and **EL 1** appears.



► Press the left side of the rocker button ▲ MEM ▼ **B** and hold down for at least 3 seconds. If the button is released earlier the clearing process will be interrupted.

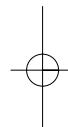


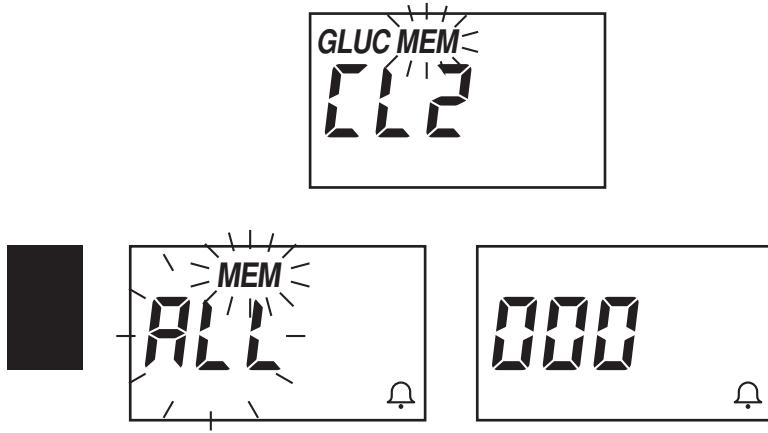
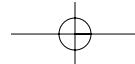
If the beeper is switched on, a series of beeps is heard (one beep per second). The most recent value measured flashes during these 3 seconds until it is cleared and **000** appears in the display **A**.



► Release the rocker button ▲ MEM ▼. **CL2** appears in the display, indicating that all values in this directory can be cleared.

To terminate the clearing procedure, briefly press the MEM ▼ button or simply switch off the meter with the ON/OFF button **C**.



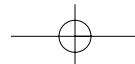
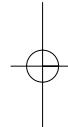


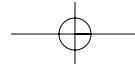
Clearing all the values stored in one directory

- ▶ If the most recent value in a directory has been cleared, it is then possible to clear all other values in this directory.

- ▶ Press the button **MEM ▲** and hold down for at least 3 seconds.
If the beeper is switched on, a series of beeps is heard (one beep per second). The word **ALL** flashes during these three seconds until the entire contents of this directory have been cleared and **000** appears in the display.

- ▶ Release the **▲ MEM ▼** button. The code number and **CODE** appear in the display.





5. Checking the performance of Accutrend® GC

5.1 Checking the measurement system

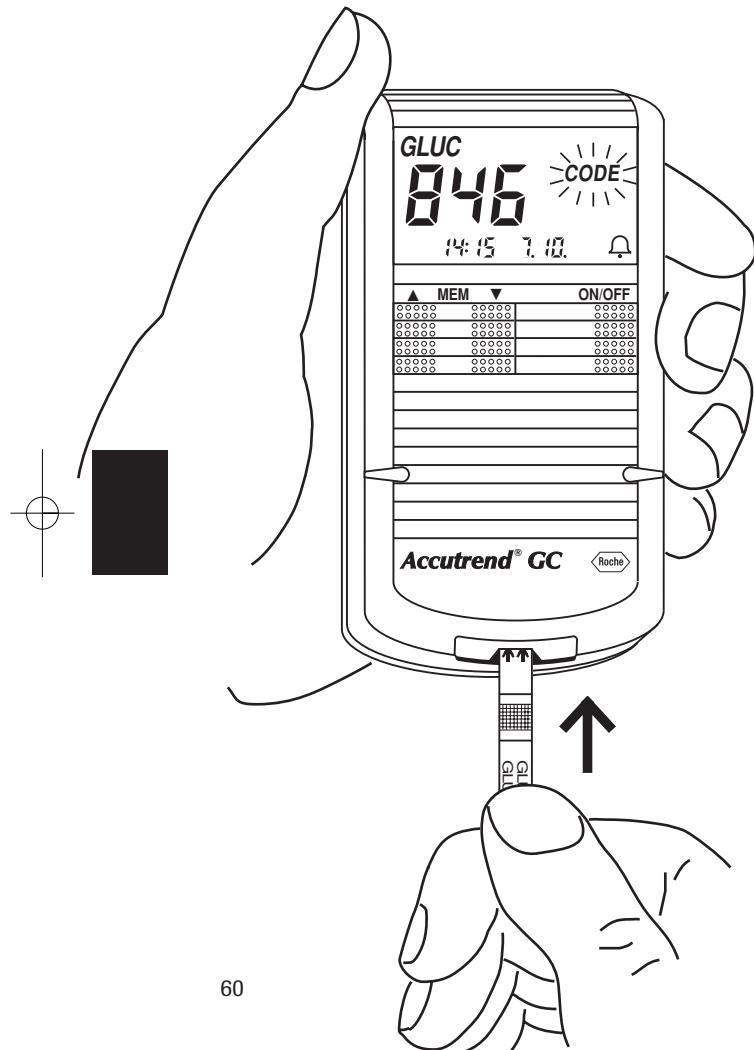
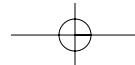
In order to obtain reliable results you must check the performance of your meter at certain times. A performance check should be carried out:

- ▶ once a week if you use the meter regularly and frequently, e.g. for blood glucose self-monitoring,
- ▶ whenever you start a new pack of test strips and therefore recode the meter (which can lead to a change in the code),
- ▶ whenever you have changed the batteries,
- ▶ after cleaning the meter,
- ▶ whenever you obtain a doubtful reading,
- ▶ in the medical setting, according to the guidelines or regulations for quality control measurements applying in your surgery or laboratory.

5.

You will need the following:

- ▶ Accutrend® GC meter.
- ▶ Accutrend® Glucose and Cholesterol test strips.



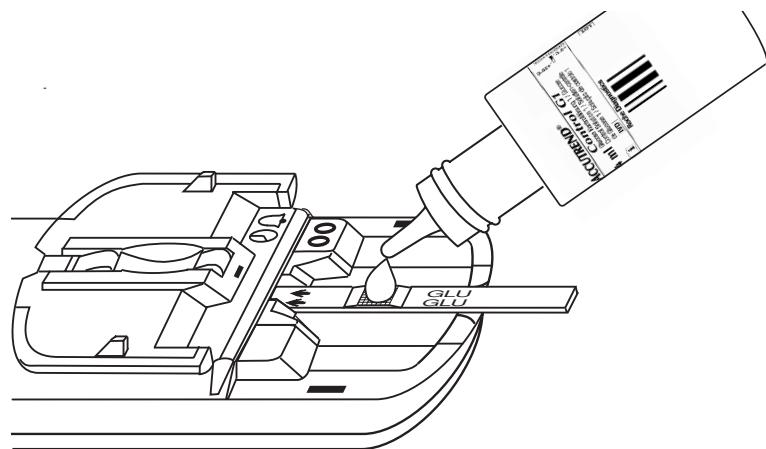
- ▶ Control solution Accutrend® Control G and Accutrend® Control CH1.

Note:

The procedure for checking the measuring system is identical to the procedure for practising how to perform a measurement. You can therefore practise performing a measurement by following the steps described below for checking the measuring system.

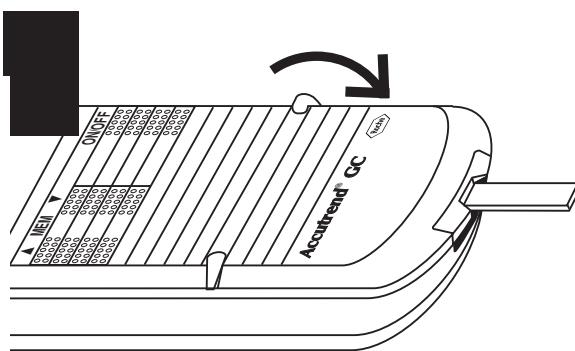
Procedure for the performance check

- ▶ Carefully read the pack inserts accompanying the test strips and control solution.
- ▶ Switch on Accutrend® GC. The meter first checks the electronics for about 2 seconds (as mentioned under 2.2) and then the word **GLUC** or **CHOL** appears in the display. These different blood components are also called "parameters". The corresponding code number, the time and the date appear below the parameter name. The word **CODE** flashes. Accutrend® GC is now ready to measure the coded parameters.
- ▶ Take a glucose test strip, for example, out of the test strip container. Close the container again immediately.



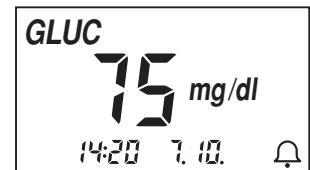
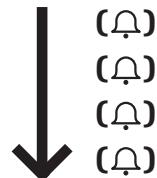
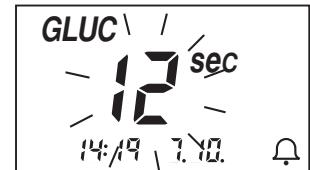
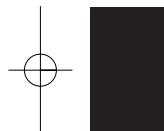
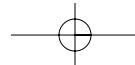
- With the flap **D** closed, insert the test strip into the slot **F** in the direction of the arrows. Make sure that the strip is inserted as far as it will go and that the word GLU on the strip can no longer be seen. When the Accutrend® GC has successfully read the strip code it emits one short and one long beep (if the beeper is switched on) and **GLUC** for Accutrend® Glucose appears on the display. **CODE** stops flashing.

If the test strip code is not read in correctly, error messages appear (e.g. **E-1**, **E-2** or **OFF**). Consult Section 6.1 and proceed according to the instructions given there. If the inserted test strip is not shown correctly on the display (e.g. if you have inserted an Accutrend® Glucose test strip but **GLUC** is not displayed), switch off the meter and start again.



- Open the flap **D**. The measurement time in seconds flashes in the display.
- Leave the test strip in the meter. Apply a large hanging drop of control solution to the yellow test pad on the strip without touching the strip directly with the bottle. The test pad must be completely wetted with solution. If the meter is used for several people, perform the function check using the procedure described for measurement with blood (see Section 3.3).

5.

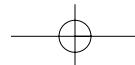
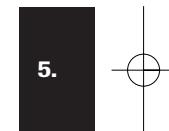


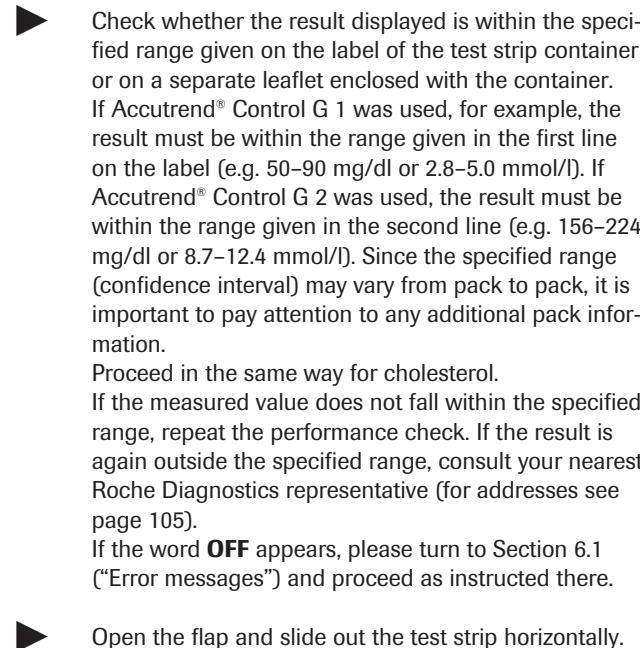
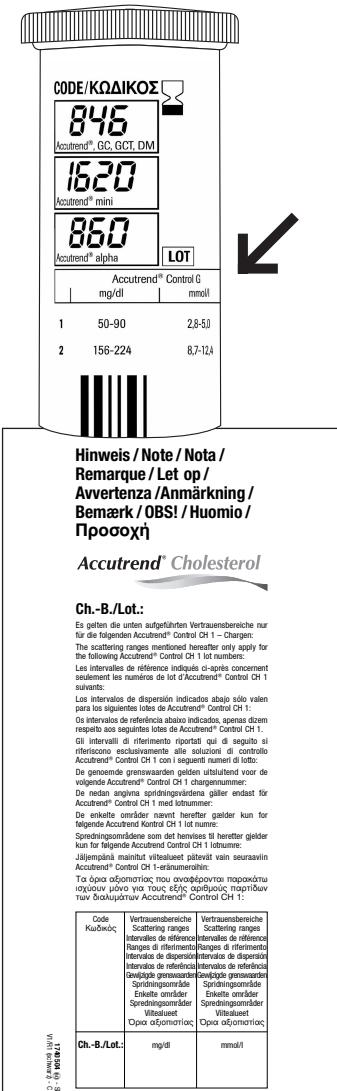
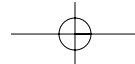
(())



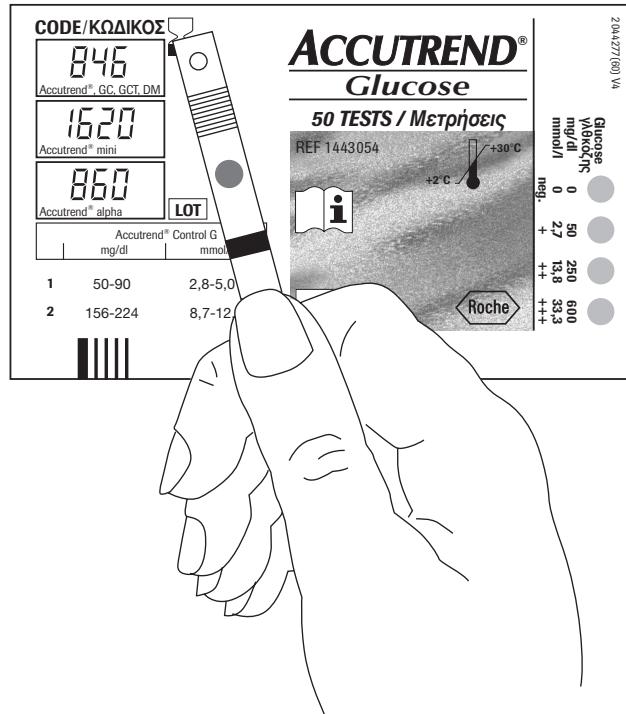
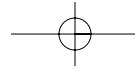
► Close the flap immediately after application of the control solution.

The display now counts down in seconds to **1**. During the last four seconds a series of beeps is heard (one beep per second) followed by a longer beep at the end of the measurement. The measured value appears in the display **A**.





4



- If you have performed the test with Accutrend® Glucose, carry out a colour comparison to check plausibility:
 - a) turn over the test strip;
 - b) compare the colour in the round window with the colour scale on the label. The colour in the round window should approximately match the colour shown for the result you have obtained.
- Close the flap and turn off the meter.

The performance check can, of course, also be carried out as described above with the control solution for cholesterol. In this case no colour comparison is performed.

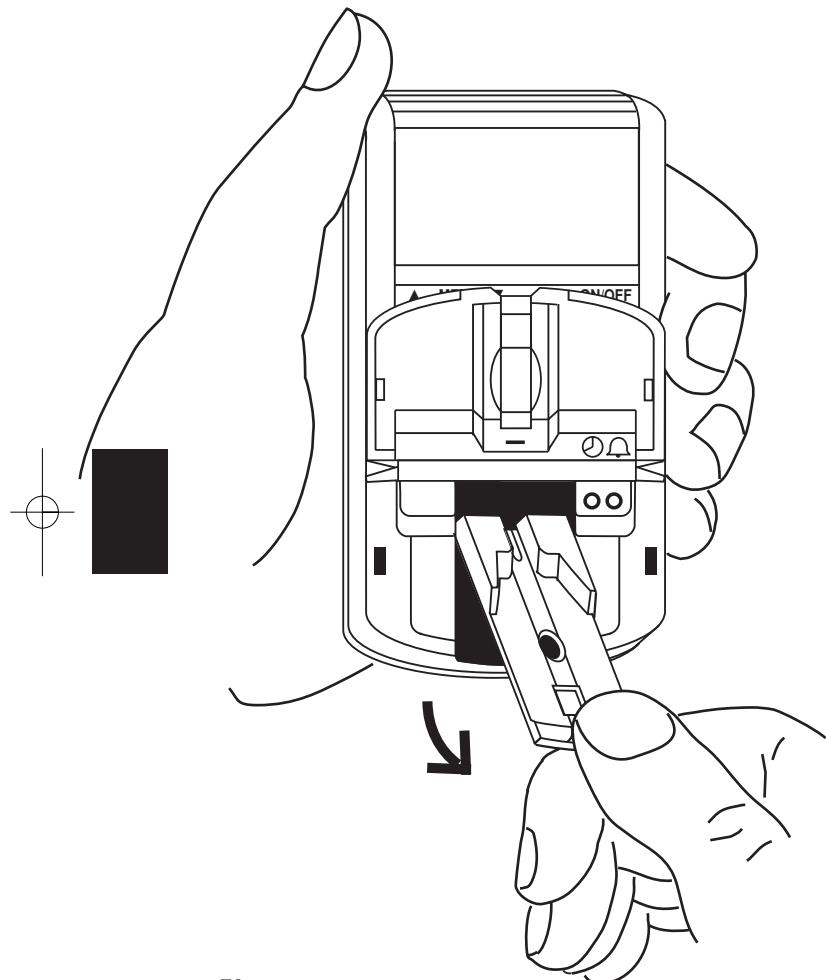
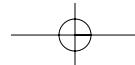
N.B.:

1. The instrument may switch itself off before you have inserted the test strip if no button has been pressed for about 60 seconds. If this happens, switch the Accutrend® GC back on and start again.
2. You may have to clean Accutrend® GC after practising (for example, if the measuring optics have become soiled).



In this case please refer to Section 5.2 and proceed as described there.

5.



5.2 Cleaning the meter

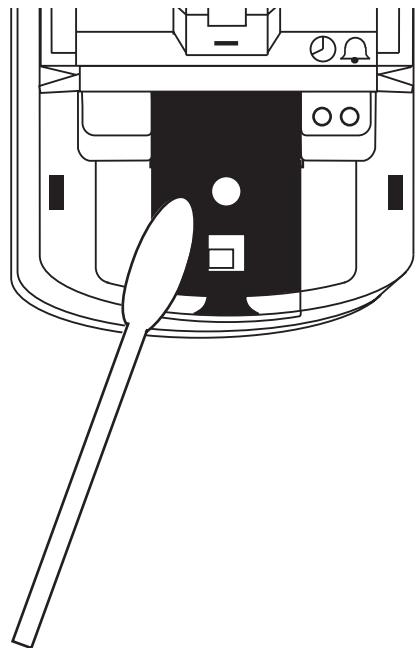
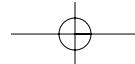
The essential prerequisite for accurate readings is cleanliness, particularly in the area around the meter's optics. The Accutrend® GC should therefore be cleaned carefully and regularly at least once a month. It should also be cleaned:

- as soon as the meter becomes dirty, paying particular attention to the flap **D** and to the test strip guide **G**;
- if the control value is outside the specified range (see Section 5.1);
- whenever you open a new pack of test strips;
- if someone else has used the meter.

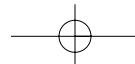
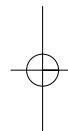
5.

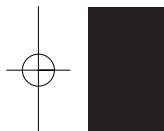
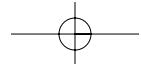
Procedure for cleaning Accutrend® GC

- ▶ Check that the meter is switched off.
- ▶ Clean the outside with a damp lint-free cotton cloth.
- ▶ Remove the test strip guide **G**. To do this, open the flap **D**, push the black guide gently in the direction of the display, lift up carefully and remove.



- ▶ After removal from the meter, clean the test strip guide with warm water and allow to dry completely.
- ▶ Gently clean the inside of the flap **D** and the entire area around the measurement window **E**, taking care not to scratch the plastic. You should therefore use only a soft, non-linting cotton cloth or cotton wool buds for cleaning. These should only be damp so as to ensure that no liquid can enter the meter.
 If 70% ethyl alcohol is used for disinfection of meters used in the medical sector, the alcohol should be wiped off again immediately after application. Use only 70% ethyl alcohol for disinfection as other agents may damage the plastic.
- ▶ Now insert the completely dry test strip guide **G** into the meter and press down gently until it clicks into place.
- ▶ Make sure that the meter functions properly after cleaning by performing a system check as described in Section 5.1.
- ⚠ Make sure that the meter, particularly the measuring window, is clean at all times as otherwise incorrect results may be obtained.





5.3 Battery life and changing the batteries

Battery life

Normally at least 1000 measurements can be performed with a fresh set of batteries. The system indicates that the batteries are running low by continuing to display **LOW BAT** after the function test. When this message appears it is still possible to perform around 50 measurements before the meter can no longer be switched on. If the power supply is interrupted for too long, all data stored in the memory will be lost. You should therefore change the batteries as soon as possible after **LOW BAT** first appears.

Changing the batteries

Always change all three batteries at the same time. It is advisable to always have a complete set of three batteries in reserve.

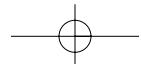
Use micro LR 03 type batteries (e.g. UCAR Micro 1.5 V AAA, KODAK Micro or VARTA Micro AAA).

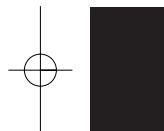
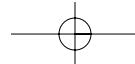
If the batteries are changed within 2 minutes no data will be lost.

Hand in used batteries at collection points, or return them to the shop for disposal.

Procedure for changing the batteries

Please proceed as described in Chapter 2.1
"Inserting/changing the batteries".





5.4 Measurement and storage conditions

Please maintain the following conditions scrupulously every time you perform a measurement. They are essential to ensure precision and reliability of the measurements.

Temperature range for measurements

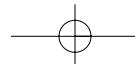
Accutrend® Glucose: +18°C to +32°C

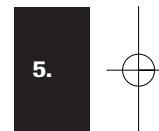
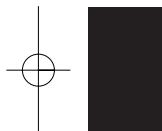
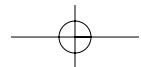
Accutrend® Cholesterol: +18°C to +30°C

If a measurement is performed at a temperature outside the ranges given above, the safety warning **LLL** flashes on the display in alternation with the measured value.

⚠ The reading was obtained under temperature conditions outside the admissible range. It must therefore be interpreted with particular caution and may only be used for orientation.

Allow the meter and test strips to adjust slowly to room temperature. Never try to speed up the temperature adjustment by placing on a radiator or in a refrigerator.





Storage conditions

Do not store the Accutrend® GC at temperatures below -25°C or above +65°C.

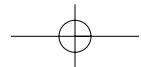
Humidity

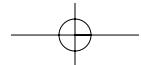
In the presence of high humidity or large temperature changes condensation may form on the meter, e.g. when it is taken from a cold to a warm environment. In such cases Accutrend® GC either switches itself off or cannot be switched on (see Section 6.1).

Allow the meter to warm up or cool down slowly at room temperature.

Possible sources of interference

Interference, e.g. frequent display of the safety warning *EEE*, cannot be ruled out in the presence of strong magnetic fields such as those induced by transmitters (CB radio devices, radios, televisions), household electrical appliances (microwave ovens, high frequency equipment), and particularly mobile telephones. It is advisable to keep the meter at least two meters away from such equipment. If the error warning continues to display after moving the meter to a different place, please contact your nearest service centre. See Section 8.4 for addresses.

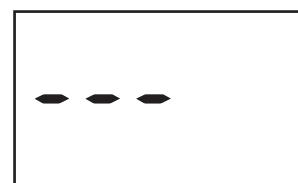




Display window



Display remains empty when you switch on the instrument



6. Troubleshooting

6.1 Error messages and important displays

Batteries have run out or have been incorrectly inserted.

- Check the batteries (see Section 2).

Humidity is too high.

- Move the meter to a dry environment and wait a while before switching it on again.

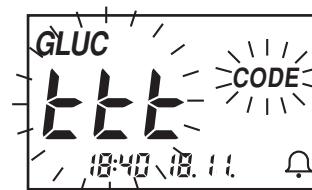
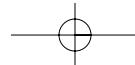
The meter is defective.

- Contact the Roche Diagnostics service centre.

No code stored.

- Code the meter (see Section 3.1).

6.



Batteries are running low.

(Does not apply during the function test)
About 50 measurements are still possible after the first appearance of **LOW BAT**.

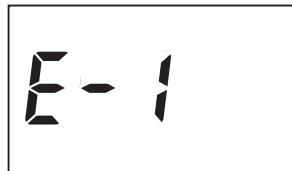
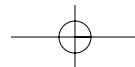
- ▶ Have new batteries ready. Always change all three batteries at the same time (see Section 5.3).

It is either too cold or too warm for a measurement.

All chemical reactions are temperature-dependent. The same applies to all test strips. The admissible temperature range is +18°C to +32°C for Accutrend® Glucose and +18°C to +30°C for Accutrend® Cholesterol. Accutrend® GC offers an additional safety warning: if a measurement is performed outside the above temperature ranges the warning 888 flashes alternately with the result. The reading may only be used for orientation.

- ▶ Let the meter and test strips adjust slowly to room temperature. Repeat the measurement within the admissible temperature range (see Section 5.4).

6.



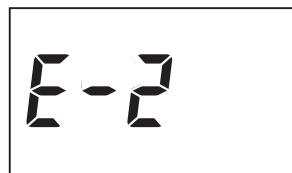
The code on the test strip does not match the code in the meter.

- ▶ Recode the meter with the code strip from the pack of test strips you are using (see Section 3.1).

The test strip is not suitable for the meter.

(e.g. a BM-Lactate test strip was used)

- ▶ Use only Accutrend® Glucose or Accutrend® Cholesterol test strips.



The reading in of the code has failed.

- ▶ Repeat the coding procedure (see Section 3.1).

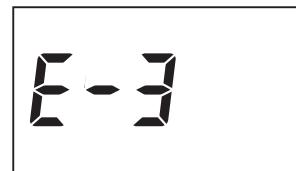
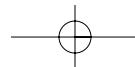
The test strip was not properly inserted.

- ▶ Open the flap, take out the strip, close the flap and insert the strip again.

6.

The flap was open during measurement.

- ▶ Repeat the entire measuring procedure with a new test strip and with the flap closed (see Section 3.2).



The code strip is not suitable for the meter.

(e.g. a BM-Lactate code strip was inserted).

- Use only Accutrend® Glucose or Accutrend® Cholesterol code strips.



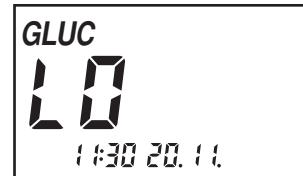
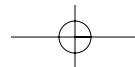
A strong magnetic field is affecting the meter.

- Move the meter to a different place (see Section 5.4).

The optics are dirty or the meter is defective.

- Clean the meter (see Section 5.2) and repeat the measurement. If the problem persists, contact the Roche Diagnostics service centre (see Section 6.3).

6.



The value is below the Accutrend® GC measuring range.

GLUC blood glucose
below 20 mg/dl (1.1 mmol/l).
CHOL cholesterol
below 150 mg/dl (3.88 mmol/l).

The round window on the back of the strip is not uniformly coloured.

(This display does not appear in every case).

► Repeat the measurement using a fresh test strip and a larger drop of blood.



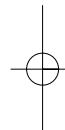
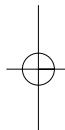
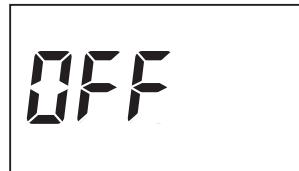
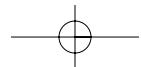
The value is above the Accutrend® GC measuring range.

GLUC blood glucose
above 600 mg/dl (33.3 mmol/l).
CHOL cholesterol
above 300 mg/dl (7.76 mmol/l).

6.

Measurement performed without a test strip.

► Insert a test strip for measurement immediately after applying the drop of blood.



The test strip has already been used.

- ▶ Use a fresh test strip.

The test strip is too old or has been incorrectly stored.

- ▶ Check the expiry date and storage conditions of the test strips. Keep the test strip container tightly closed at all times.
For Accutrend® Glucose only: check for discolouration of the unused strip by comparing the colour of the round window on the back of the strip with the colour scale on the label of the Accutrend® Glucose test strip container. The yellow colour of the round window on the back of the strip should match the yellow colour indicating "neg" on the label. If the colour of the test window is darker, the test strip may not be used.

6.

The test strip guide is dirty.

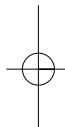
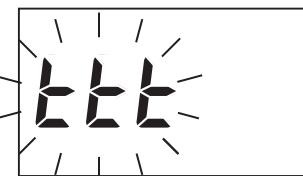
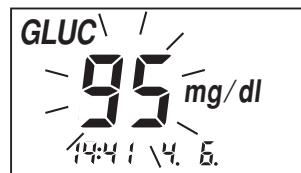
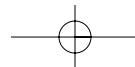
- ▶ Clean the guide carefully (see Section 5.2).

No blood was applied to the test strip.

- ▶ Repeat the measurement applying a drop of blood to the strip (see Section 3.2).

Too much ambient light.

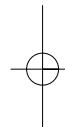
- ▶ Move the meter to a darker place.



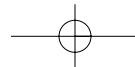
If the message **ETT** is displayed alternately with the result, this means that you have performed a measurement outside the permissible temperature range.

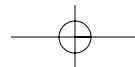
- ▶ Allow the meter and the test strips to adjust to room temperature slowly. Never try to speed up the temperature adjustment by placing on a radiator or in the refrigerator.

Ready for deletion of the most recent result from memory.



Ready for deletion of all results from a directory.



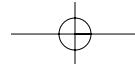


All results will be deleted from the memory within three seconds (unless the MEM ▼ button is released earlier).



Ready for setting the date and time or the beeper.





6.2 Possible causes of errors

If the meter repeatedly displays error messages, or often gives unexpected results, please check the following:

- Have you checked the batteries?
- Was the measurement performed according to the instructions?
- Have the test strips been stored and handled in accordance with the package insert?
- Has the shelf life of the test strips or the control solutions expired?
- Are the test strip guide and measurement window clean?
- Were the test strips always from a pack whose code number is displayed by the meter?

If you have checked these points and still obtain error messages or doubtful values, please contact your dealer or nearest service centre. See Section 8.4 for addresses.

6.3 Roche Diagnostics service

Advisory service: For all questions about what to do if implausible values are obtained or if the meter is thought to be defective, please contact our advisory service.

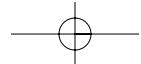
The staff there will try to help you solve the problem. A list of Roche Diagnostics representatives in the different countries is given in Section 8.4.

Repair service: Please note that any repairs or adjustments to the meter, or any further modifications should only be carried out by persons authorized by Roche Diagnostics.

If you suspect a fault in your meter you should first contact the advisory service at your nearest Roche Diagnostics office. The staff there will try to sort out the problem with you on the telephone.

In exceptional cases problems cannot be cleared up on the telephone. If this is the case, you should send your Accutrend® GC meter to your nearest Roche Diagnostics office together with the test strips used and – if the meter is still under guarantee – the warranty card.

6.



7. Additional information for medical personnel and laboratories

7.1 Measuring principle

An unused test strip is inserted into the meter. Light from an LED (light emitting diode) is directed towards the test strip from below and the blank value of the test strip determined by measurement of the reflected light. Then a small drop of blood is applied to the test area on the strip.

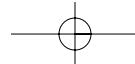
If the blood is to be applied outside the meter the procedure described in Chapter 3.3 is used.

The constituent to be determined in the applied sample undergoes an enzymatic reaction with formation of a dye, the amount of dye formed increasing with the concentration of the substance to be determined. After a certain period of time, which is dependent on the test being performed, the meter measures the colour intensity. This is done by directing light from an LED towards the test area from below and measuring the intensity of the reflected light with a detector.

For calculation of the result, the signal of the reflected light is analyzed in relation to the initially measured blank value with the help of the information programmed into the meter and the information read into the meter from the code strip belonging to the respective test strip pack.

The result is then displayed.

7.



7.2 Software

Apart from the software programmed into the meter for performance and analysis of the test and the software for the automatic checks performed by the meter, Accutrend® GC also contains software that allows you to select and call up various basic settings and recurring functions using the buttons on the meter.

The individual steps for performing these operations are described in the respective chapters. The information appearing on the display is also described or shown there.

7.3 Downloading data to a PC

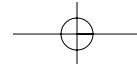
Accutrend® GC allows transmission of the stored values to suitable computer programs via an integrated serial interface.

 shows the position of the connector for data transmission. With the help of this software, data can be exported from Accutrend® GC and saved. For further information on this please contact Roche Diagnostics.

8. General information

8.1 Technical data

| | |
|------------------------|------------------------------------------------------------------------------------------------------------------------|
| Type: | Accutrend® GC |
| Serial No.: | See name plate (on underside of instrument) |
| Measurement principle: | Determination of glucose or cholesterol in fresh capillary blood by reflectance photometry. |
| Optical system: | LED (657 nm) |
| Measurement range: | Glucose 20–600 mg/dl (1.1–33.3 mmol/l) |
| | Cholesterol 150–300 mg/dl (3.88–7.76 mmol/l) |
| Measurement time: | Glucose 12 seconds |
| Memory capacity: | Cholesterol 180 seconds 50 blood glucose results 15 cholesterol results, all values with time and date |
| Dimensions: | 115 x 62 x 18.5 mm |
| Weight: | Approx. 90 g (without batteries) |
| Display: | Liquid crystal display |
| Automatic cut-off: | After 2 minutes with test strip inserted; after 1 minute if no button was pressed and no test strip has been inserted. |
| Data output: | 3-pin connector, serial |
| Power supply: | 3 x 1.5 V batteries type: micro LR 03, e.g. UCAR Micro 1.5 V AAA, KODAK Micro or VARTA Micro AAA. |



Battery life:
Storage conditions:

Disposal:

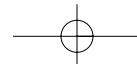
CE 0088

This Accutrend® GC meter has been designed and tested in accordance with German standards for electronic instruments (DIN, VDE, IEC). The meter left the factory in perfect compliance with the specified safety regulations. In order to preserve this condition and to ensure reliable operation, the user must observe the safety warnings in these operating instructions.

The manufacturer reserves the right to modify the system.



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8.2 System components

For measurement of blood glucose with Accutrend® GC use only **Accutrend® Glucose** test strips. These are available in different pack sizes. For further information please ask your pharmacist or your Roche Diagnostics office.

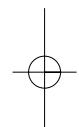
For measurement of cholesterol with the Accutrend® GC use only **Accutrend® Cholesterol** test strips.

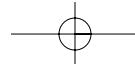
For performance checks with control solutions use only **Accutrend® Control G** and **Accutrend® Control CH1**.

Recommended lancing device: the Accu-Chek® Softclix® Pro lancing device with matching lancets **Accu-Chek® Softclix® Pro Lancet**, which are specially designed to make blood collection virtually pain-free.

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8.3 Manufacturer's warranty and guarantee

Manufacturer's warranty: Roche Diagnostics guarantees the proper functioning of your Accutrend® GC to the extent defined in the completed warranty card supplied with the instrument, on completion and return of said warranty card. For precise terms and conditions please see the warranty card. This does not affect your statutory or other rights.

The warranty covers any material and manufacturing defects that arise during proper use of the instrument and are discovered and reported within the warranty period. The warranty does not cover any interference with the instrument or any case of improper use or maintenance.

We undertake, at our discretion, to repair faulty components free of charge or provide a fault-free replacement meter.

Statutory and other rights: The manufacturer's warranty given above is in addition to any statutory or other rights granted through your dealings with the instrument supplier.

8.4 International addresses

Roche Diagnostics GmbH

D-68298 Mannheim

Germany

Tel.: +49 (621) 7 59 46 46

Roche Diagnostics Australia

Pty Ltd., 31 Victoria Avenue, Castle Hill, NSW 2154

AUSTRALIA

Extracare Enquiry line: 1800 251816

Roche Diagnostics

201 Boul. Armand-Frappier, H7V 4A2, Laval, Québec

CANADA

Tel. 1-800-363-5880 (hotline)

Roche Diagnostics N.Z.

Ltd, 15 Rakino Way, Box 62-089, Mt. Wellington

Auckland, **NEW ZEALAND**

Tel. 0800-802-299

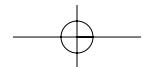
Roche Diagnostics Ltd

Bell Lane, Lewes

East Sussex, BN7 1LG, **UNITED KINGDOM**

Freephone: 0800 701 000

Freephone Rep. of Ireland: 1800 709 600



9. Index

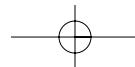
Roche Diagnostics K.K., Nippon Roche Building 6-1
Shiba 2-chome, 105-0014 Minato-ku, Tokyo, **JAPAN**

Roche Diagnostics Asia Pacific Pte. Ltd.
298, Tiong Bahru Road
#16-01-06 Tiong Bahru Plaza
Singapore 168730
Tel. +652727500

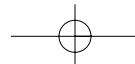
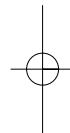
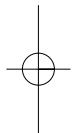
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Accutrend® GC Warranty Card

To be completed by the dealer.

If the warranty card was not completed at the time of purchase, please keep the receipt and submit together with the meter in the event of claims.

On presentation of this card Accutrend® GC is guaranteed by Roche Diagnostics GmbH for **twelve months** from the date of purchase against defects in materials or workmanship which occur on proper use of the instrument and occur and are reported during the warranty period. The warranty ceases to apply if the instrument is damaged by tampering, misuse or negligent maintenance.

Our liability under this warranty is limited to the repair of defective parts or to the provision - at our option - of a correctly functioning replacement instrument.

This warranty is only valid if the date of purchase, and the stamp and signature of the dealer are entered on this card at the time of purchase or if the original receipt is submitted. The warranty period is not extended by any claim made under this warranty.

Serial No. _____

Date of purchase _____

Stamp and signature of dealer _____

Warranty Card

Name _____

Street _____

City/post code _____

Telephone No. _____

Date _____

Signature _____